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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,052	11/01/2006	Paul William Glue	33427-US-PCT	6943
67283 7590 07/07/2009 MONTGOMERY, MCCrackEN, WALKER & RHOADS, LLP 123 SOUTH BROAD STREET AVENUE OF THE ARTS PHILADELPHIA, PA 19109				
EXAMINER SPIVACK, PHYLLIS G				
ART UNIT		PAPER NUMBER		
1614				
MAIL DATE		DELIVERY MODE		
07/07/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/576,052

**Applicant(s)**

GLUE ET AL.

**Examiner**

Phyllis G. Spivack

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Applicants' Request for Continued Examination (RCE) filed June 30, 2009 under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), is acknowledged and accepted.

Claims 1-8 are pending.

Claims 1-8 remained rejected under 35 U.S.C. 103(a), as being unpatentable over Doi et al., US 2004/0058914, in the last Office Action. It was asserted Doi teaches the administration of the neurokinin receptor antagonist DNK 333, which is N-[(1R,2E)-1-[(3,4-dichlorophenyl)methyl]-4-[[[(3R)-hexahydro-2-oxo-1H-azepin-3-yl]amino]-4-oxo-2-buten-1-yl]-N-methyl-3,5-bis(trifluoromethyl)-benzamide, the compound of instant claim 7, in the treatment of urinary frequency and urinary incontinence. See claims 1, 5 and 6, pages 29-30. In paragraph 393 on page 20, Doi teaches administration of a NK<sub>1</sub>-NK<sub>2</sub> dual antagonist, such as DNK 333 alone, or in combination with an anti-cholinergic.

Applicants argue there is no experimental evidence in Doi to support a method of treating urinary incontinence, and the model used in the Doi reference is not a model for urinary incontinence. Further, Applicants cite Green et al., The Journal of Urology, that is directed to the administration of an NK<sub>1</sub> receptor antagonist alone to treat urge urinary incontinence. Applicants characterize Green's experimental results as "inconsistent."

Applicants' arguments have been given careful consideration but are not found persuasive. The rejection of claims 1-8 under 35 U.S.C. 103(a) as being unpatentable over Doi et al., US 2004/0058914, is maintained. Methods of treating urinary incontinence comprising administering DNK 333, N-[(1R,2E)-1-[(3,4-dichlorophenyl)methyl]-4-[[[(3R)-hexahydro-2-oxo-1H-azepin-3-yl]amino]-4-oxo-2-buten-1-

yl]-N-methyl-3,5-bis(trifluoromethyl)-benzamide, is clearly contemplated by Doi, as evidenced by the multiple recitations thereto throughout the disclosure, as well as in the claims. See page 29, paragraph [0506].

The Green article describes the administration of the NK<sub>1</sub> receptor antagonist, aprepitant, which is not an NK<sub>1</sub>-NK<sub>2</sub> dual antagonist, and not structurally related to the specific antagonist DNK 333. Therefore, the comparison is misplaced and without merit.

A reference may be applied not only for what it teaches by direct anticipation, but also for what one of ordinary skill in the art, at the time of the invention, might reasonably infer from the teachings. See *In re Opprecht*, 12 USPQ 2d, 1235, 1236 (Fed. Cir. 1989) and *In re Bode*, 193 USPQ 12 (CCPA 1976).

Motivation is provided to administer the NK<sub>1</sub>-NK<sub>2</sub> dual antagonist DNK 333 to treat urinary incontinence based on the teachings and suggestions of the Doi document.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 2, 2009

/Phyllis G. Spivack/

Primary Examiner, Art Unit 1614